This is a level 2 guidance document under FDA's Good Guidance Practices policy. This guidance document does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

II. Electronic Access

In order to receive the ''Medical Device Appeals and Complaints: A Guidance On Dispute Resolution'' guidance document via your fax machine, call the CDRH Facts-on-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt, press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number (396) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance document may also do so by using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. The CDRH home page is updated on a regular basis and includes the ''Medical Device Appeals and Complaints: A Guidance On Dispute Resolution'' guidance document, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Medical Device Appeals and Complaints: A Guidance On Dispute Resolution'' is also available on the medical device reporting page at http://www.fda.gov/cdrh/modact/modern.html.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there, follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there, select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

III. Request for Comments

Interested persons, may at any time, submit to the contact person listed above written comments regarding this guidance document. Comments will be considered in determining whether to revise or revoke the guidance.

Dated: February 11, 1998.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–4842 Filed 2–20–98; 4:00 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98D–0078, 98D–0079, 98D–0080, 98D–0081, 98D–0082, and 98D–0083]

FDA Modernization Act of 1997; Guidance Documents for the Medical Device Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of six guidance documents that represent the Center for Devices and Radiological Health's (CDRH) initial approach to implementation of revelant sections of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115). Many of the procedural changes for CDRH that are required by the FDAMA are being implemented initially through these six guidance documents. Due to the timing of the required implementation, the use of guidance documents is the most expeditious way to initially implement the FDAMA. The agency requests comments on these six guidance documents.

DATES: Submit written comments by May 26, 1998. After the close of the comment period, written comments may be submitted at any time to Ron Jans (address below)

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number for the appropriate guidance document found in the SUPPLEMENTARY INFORMATION section. Submit written requests for an IBM PC compatible diskette containing the documents to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

For information on this document contact: Ronald P. Parr, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–7491, ext. 128.

To submit comments after the close of the comment period contact: Ron Jans, Center for Devices and Radiological Health (HFZ–205), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3744.

SUPPLEMENTARY INFORMATION:

I. Background

The FDAMA was signed by the President on November 21, 1997. Several of the provisions of FDAMA go into effect 90 days after enactment. CDRH has issued a guidance document outlining the general approaches FDA intends to take to implement the highest priority provisions of the new law. FDA published a notice of availability of this general guidance (referred to as the ''Day 1 guidance'') in the **Federal Register** of February 6, 1998 (63 FR 6193).

The agency is announcing the availability of the following six guidance documents (each with a separate docket number) that represent CDRH's initial approach to implementation of the various relevant sections of the FDAMA:

(1) ''Early Collaboration Meetings Under the FDA Modernization Act (FDAMA), Guidance for Industry and CDRH Staff, Final Document'' (Docket Number 98D–0078) (FOD # 310),

(2) ''Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies—for Use by CDRH and Industry'' (Docket Number 98D–0079) (FOD # 322),

(3) ''30-Day Notices and 135-day PMA Supplements for Manufacturing Method or Process Changes, Guidance for Industry and CDRH'' (Docket Number 98D–0080) (FOD # 795),

(4) ''Determination of Intended Use for 510(k) Devices; Final Document'' (Docket Number 98D–0081) (FOD # 857),

(5) ''New section 513(f)(2)—Evaluation of Automatic Class III Designation; Guidance for Industry and

CDRH Staff'' (Docket Number 98D–0082) (FOD # 199), and

(6) ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (Docket No. 98D–0083) (FOD # 159).

These guidance documents represent the agency's current thinking on CDRH's implementation of the FDAMA. These guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both. Under FDA's ''Good Guidance Practices'' policy (62 FR 8961, February 27, 1997), each of these guidance documents is a Level 1 guidance document that may be implemented immediately because it is the subject of a new statute. FDA will review the comments received in order to determine whether to revise or revoke the guidance.

These guidance documents may contain collections of information that require OMB clearance under the Paperwork Reduction Act of 1995. FDA will seek such approval and provide an opportunity to comment, as appropriate.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the World Wide Web for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. Updated on a regular basis, the CDRH Home Page includes these guidance documents, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh/modact/modern.html.

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In order to receive these guidance documents via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number followed by the pound sign (#). The appropriate FOD number is listed next to the title of the document in the list above. Then follow the remaining voice prompts to complete your request.

III. Comments

Interested persons may, by or before May 26, 1998 submit to the Dockets Management Branch (address above) written comments regarding these guidance documents. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number for each guidance listed next to the title of the document in the list found previously. If you wish to comment on more than one guidance document, please submit a separate comment for each guidance document for which you wish to submit a comment. The guidance documents and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

After May 26, 1998, written comments may be submitted at any time to Ron Jans (address above).

Dated: February 12, 1998

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–4841 Filed 2–20–98; 4:00 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98D–0106, 98D–0107, 98D–0108]

Medical Devices; Postmarket Surveillance; Guidance Documents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of three guidance documents on postmarket surveillance of medical devices. These guidance documents are being issued in order to facilitate the implementation of the postmarket surveillance provisions of the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997. FDA will issue further guidance in the near future.

DATES: Submit written comments concerning these guidance documents by May 26, 1998.

ADDRESSES: Submit written to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written requests for single copies of these guidance documents on a 3.5'' diskette to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to these guidance documents.

FOR FURTHER INFORMATION CONTACT: Anita Rayner, Center for Devices and Radiological Health (HFZ–543), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–0639.

SUPPLEMENTARY INFORMATION:

I. Background

The Safe Medical Devices Act of 1990 amended the act, among other things, to add section 522 (21 U.S.C. 360(l)) to require postmarket surveillance for certain medical devices. Section 522 was further amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115). As amended, section 522 of the act revises the criteria for determining which devices are subject to postmarket surveillance and revises the procedures for implementing postmarket surveillance. The revised provisions of section 522 become effective on February 19, 1998.

FDA is making the following guidance documents available at this time in order to facilitate the initial implementation of the revised postmarket surveillance provisions:

1. Guidance on Procedures to Determine Application of Postmarket Surveillance Strategies (Docket No. 98D–0106 (FOD # 316));

2. Guidance on Procedures for Review of Postmarket Surveillance Submissions (Docket No. 98D–0107 (FOD # 317)); and